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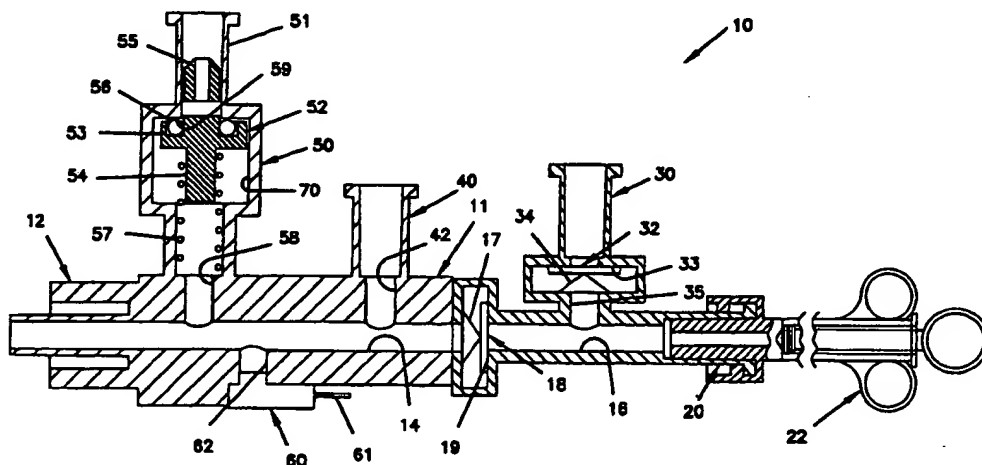
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁷ : A61M 39/24</p>	<p>A1</p>	<p>(11) International Publication Number: WO 00/16849</p> <p>(43) International Publication Date: 30 March 2000 (30.03.00)</p>
<p>(21) International Application Number: PCT/US99/21980</p> <p>(22) International Filing Date: 22 September 1999 (22.09.99)</p> <p>(30) Priority Data: 09/159,008 23 September 1998 (23.09.98) US</p> <p>(71) Applicant: MAYO FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH [US/US]; 200 First Street Southwest, Rochester, MN 55905 (US).</p> <p>(72) Inventors: SCHWARTZ, Robert, S.; 1123 Aubaz Lane S.W., Rochester, MN 55902 (US). HOLMES, David, R.; 1122-21st Street N.E., Rochester, MN 55906 (US). BERRY, David; 1240-60th Street S.W., Rochester, MN 55902 (US). ELLIS, Donald, G.; 519 Pluto Drive, Colorado Springs, CO 80906 (US).</p> <p>(74) Agent: BRUESS, Steven, C.; Merchant & Gould P.C., 3100 Norwest Center, 90 South Seventh Street, Minneapolis, MN 55402-4131 (US).</p>		<p>(81) Designated States: AE, AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), DM, EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published</p> <p><i>With international search report.</i></p> <p><i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>

(54) Title: AUTOMATIC MANIFOLD FOR VASCULAR CATHETER



(57) Abstract

An automatic manifold for a catheter assembly. Valve means automatically open and close flow between a liquid supply port for connection to injection means and a liquid delivery port for communication with the catheter assembly. A pressure sensor is integrated into the manifold. The manifold also includes a quick-disconnect coupling mechanism for a liquid supply port.

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AUTOMATIC MANIFOLD FOR VASCULAR CATHETER

Field of the Invention

This invention relates generally to devices used with vascular catheters, and more particularly to manifolds for delivering liquids to the patient
5 through the catheter.

Background of the Invention

Manifolds for delivering liquids, such as contrast media, saline and drugs, through a catheter are known in the art. The manifold has a number of ports through which different liquids are supplied and an outlet port through which liquid
10 is delivered. A device, such as a power injector or syringe, connected to another port, draws liquid from a selected supply port and then forces the liquid into the catheter via the delivery port. The manifold thus acts as a traffic-keeping device of sorts which is manipulated by the operator to deliver different liquids to the patient as needed.

15 One of the problems associated with the manifolds in use today is that the valves employed to direct liquids are fully manual. For example, the MORSE® MANIFOLD most commonly used employs manual stopcock valves to control flow from the various liquid supply ports, to and from the injector, and to the liquid delivery port. Each time it is desired to deliver a particular liquid to a patient, one or
20 more of these stopcocks first must be manually moved to draw liquid into the injector, and then again must be manually moved to inject the liquid into the catheter. This wastes time, which is particularly valuable when performing diagnostic, therapeutic or interventional vascular procedures, is a distraction during such procedures, and requires the use of an extra hand. There is also the possibility
25 that the stopcocks could accidentally be moved to the wrong positions such that the wrong fluid is delivered, an air bubble is created, or some other risk to the patient occurs. These risks are of particular concern as nonphysicians become more involved with procedures.

What has been needed is a manifold for a catheter assembly which
30 automatically controls flow between the liquid supply ports and the liquid delivery port when injecting liquid into the patient.

Summary of the Invention

According to the present invention, an automatic manifold for a catheter assembly is provided. The automatic manifold could be employed in a variety of venous medical device assemblies, including cardiac, neurological and
5 arterial applications.

In one aspect of the invention, the automatic manifold comprises a housing having a liquid delivery port for communication with the catheter assembly, and a liquid supply port for connection to an injector. A chamber defined in the housing is in fluid communication with the liquid delivery and supply ports. A one-
10 way valve controls flow between the supply and delivery ports and through the chamber. The valve is biased toward a closed position and is constructed and arranged to move to an open position when liquid is forced into the supply port under pressure.

In another aspect of the invention, the automatic manifold comprises
15 a liquid delivery port for communication with a catheter assembly, and a liquid supply port for connection to an injector. A valve mechanism automatically opens flow between the supply and delivery ports when liquid is forced into the supply port under pressure, and automatically closes flow between the supply and delivery ports when liquid no longer is forced into the supply port.

20 These and other advantages and features of novelty which characterize the invention are pointed out with particularity in the claims annexed hereto. However, for a better understanding of the invention and its advantages, reference should be made to the drawing which forms a further part hereof, and to the accompanying descriptive matter in which there is illustrated and described a
25 preferred embodiment of the invention.

Brief Description of the Drawings

Figure 1 is a cross-sectional view of an automatic manifold according to the present invention.

Detailed Description of the Preferred Embodiment

30 Referring now to the drawings, an embodiment of the automatic manifold of the present invention is shown in Fig. 1.

Manifold 10 comprises housing 11 including liquid supply 20 and delivery 12 ports connected by first 14 and second 16 chambers. Check valve 18

between chambers 14, 16 controls flow between supply 20 and delivery 12 ports. Valve 18 is a one-way valve known (see U.S. Patent No. 4,535,820) and available (from Burrion Medical Inc. of Bethlehem, Pennsylvania) for medical applications. Valve 18 is made of elastomeric material supported by conical member 17 against seating surface 19 to a closed position (shown). When liquid is forced under pressure into supply port 20 by syringe 22, valve 18 automatically opens (by lifting from surface 19) to allow the liquid to pass into chamber 14, out delivery port 12 and into the catheter (not shown). After liquid is no longer being forced through valve 18 by syringe 22, valve 18 automatically closes (against surface 19) so as to isolate supply port 20 (and second chamber) from first chamber 14.

First liquid supply port 30 communicates with second chamber 16 via passage 35, flow being controlled by another one-way valve 32 including a conical member 34 and seating surface 33. When syringe 22 draws liquid from second chamber 16, valve 18 automatically stays closed and valve 32 automatically opens so that liquid is drawn into first supply port 30, through second chamber, and into syringe 22. When syringe 22 is depressed, valve 32 automatically stays closed and valve 18 automatically opens as discussed above.

Employing one or more automatic one-way valves in this way permits supplying liquids to the patient without having to manually manipulate various valves. The necessary opening and closing between ports, chambers and/or passages is automatically done simply by operating an injector to draw in and then force out liquid.

It will be understood that the makeup of, and arrangement of, the various components could be varied to achieve similar results. For example, first supply port 30 (or additional supply ports) need not necessarily have a one-way valve, but could use a manual or another valve control means. A power injector, or other pressure-generating device, could be employed instead of a syringe. Various automatic one-way valve designs could be employed.

In the preferred embodiment, there are four liquid supply ports 20, 30, 40, 50 (not including the syringe port 20), only one (30) of which has a one-way valve 32. The latter three (30, 40, 50) act as inlets for different liquids, specifically contrast media, saline, and drugs, respectively, in the preferred embodiment. It will be understood that these ports could be rearranged, some taken away, or others added, within the principles of the invention. Further one-way valves associated with particular ports, in various arrangements, could also be employed.

Second supply port 40 communicates with first chamber 14 via passage 42. This port is intended for saline flushing liquid, such as a slow continuous flush, a fast periodic flush, or both.

Third supply port 50 is intended for drug delivery and includes a novel coupling mechanism 52. When a standard threaded male Luer (such as 12, threads not shown) is threaded onto female Luer 51, the central protrusion of the male Luer (see 12 again) abutts against head 55 and compresses spring 57 on stem 54 of plunger 53, thereby moving O-ring 56 away from seat 59. Liquid then flows into and around head 55 and around the rest of plunger 53, through chamber 70 and passage 58, and into first chamber 14. When the male Luer is unthreaded, spring 57 automatically returns coupling mechanism 52 to a closed position (shown). In this way, a reliable and simple seal is created where, as when introducing drugs, it is desired to have the capability to quickly connect different liquid sources to, and disconnect them from, the manifold. It will be understood that the components of coupling 52, and their arrangement, could be varied within the principles of the invention.

When liquid is injected into either second 40 or third 50 supply ports, valve 18 automatically stays closed.

Manifolds known today are connected to a pressure sensor/monitor via another port and a line communicating liquid from the manifold to the sensor/monitor. This is undesirable because readings can sometimes be inaccurate (due to the liquid in the line limiting frequency response, or due to a bubble in the line) and the additional line can be cumbersome. The novel design herein accordingly incorporates a pressure sensor 60 directly into the manifold. Sensor 60 employs a pressure transducer (such as the Motorola MPX2300D) which senses pressure directly from chamber 14 and transmits an electronic signal to a monitor (not shown) via electrical leads 61.

It will be understood that the last three components discussed (40, 50, 60) could be arranged in different locations. For example, 40 or 50 could be located on an upstream side of valve 18 in communication with second chamber 16. Various other arrangements could also be imagined.

It should be understood that the present invention is not limited to the preferred embodiment discussed above, which is illustrative only. Changes may be made in detail, especially in matters of the type, arrangement, shape and size of

components within the principles of the invention, to the full extent indicated by the broad general meanings of the terms in which the appended claims are expressed.

WE CLAIM:

1. An automatic manifold for a catheter assembly, comprising:
 - (a) a housing having a liquid delivery port for communication with the
5 catheter assembly and a liquid supply port for connection to an injector;
 - (b) a chamber defined in said housing in fluid communication with said
liquid delivery and supply ports; and
 - (c) a one-way valve for controlling flow between said supply and
10 delivery ports and through said chamber, biased toward a closed position, and
constructed and arranged to move to an open position when liquid is forced into said
supply port under pressure.
2. An automatic manifold according to claim 1, wherein said one-way valve is
15 on an upstream side of said chamber.
3. An automatic manifold according to claim 2, wherein said one-way valve
separates said chamber from a second chamber located on an upstream side of said
one-way valve, and said second chamber has a plurality of liquid supply ports.
- 20 4. An automatic manifold according to claim 3, wherein at least one of said
liquid supply ports has associated with it a second one-way valve, biased toward a
closed position, and constructed and arranged to move to an open position when
liquid is forced by said injector from said one supply port to said second chamber.
- 25 5. An automatic manifold according to claim 1, further including a second
liquid supply port constructed and arranged for receiving contrast media.
6. An automatic manifold according to claim 1, further including a second
liquid supply port constructed and arranged for receiving saline.
- 30 7. An automatic manifold according to claim 1, further including a second
liquid supply port constructed and arranged for receiving drugs.
8. An automatic manifold according to claim 1, wherein said injector is a power
35 injector.

9. An automatic manifold according to claim 1, wherein said injector is a syringe.
- 5 10. An automatic manifold according to claim 1, further including a pressure port connecting said first chamber to a pressure monitor.
11. An automatic manifold according to claim 10, wherein said pressure monitor comprises a pressure sensor integrated as part of the manifold.
- 10 12. An automatic manifold according to claim 1, wherein said housing has a plurality of liquid supply ports.
13. An automatic manifold according to claim 12, wherein said plurality of liquid supply ports includes a saline port and a contrast media port, at least one of which has associated with it a second one-way valve.
- 15 14. An automatic manifold according to claim 1, wherein said one-way valve comprises an elastomeric material.
- 20 15. An automatic manifold for a catheter assembly, comprising:
(a) a liquid delivery port for communication with the catheter assembly;
(b) a liquid supply port for connection to injection means; and
(c) valve means for automatically opening flow between said supply and
25 delivery ports when liquid is forced into said supply port under pressure, and for automatically closing flow between said supply and delivery ports when liquid no longer is forced into said supply port.
16. An automatic manifold according to claim 15, wherein said valve means
30 comprise a mechanical one-way valve.
17. An automatic manifold according to claim 15, further including a first chamber defined in said manifold in fluid communication with said liquid delivery and supply ports, wherein said valve means are on an upstream side of said first
35 chamber.

18. An automatic manifold according to claim 17, wherein said valve means separate said first chamber from a second chamber located on an upstream side of said valve means, and said second chamber has a plurality of liquid supply ports.

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19. An automatic manifold according to claim 15, wherein said automatic manifold has a plurality of liquid supply ports, including a saline port and a contrast media port, operating in conjunction with said valve means comprising one or more separate valve means, to automatically open and close flow between said liquid

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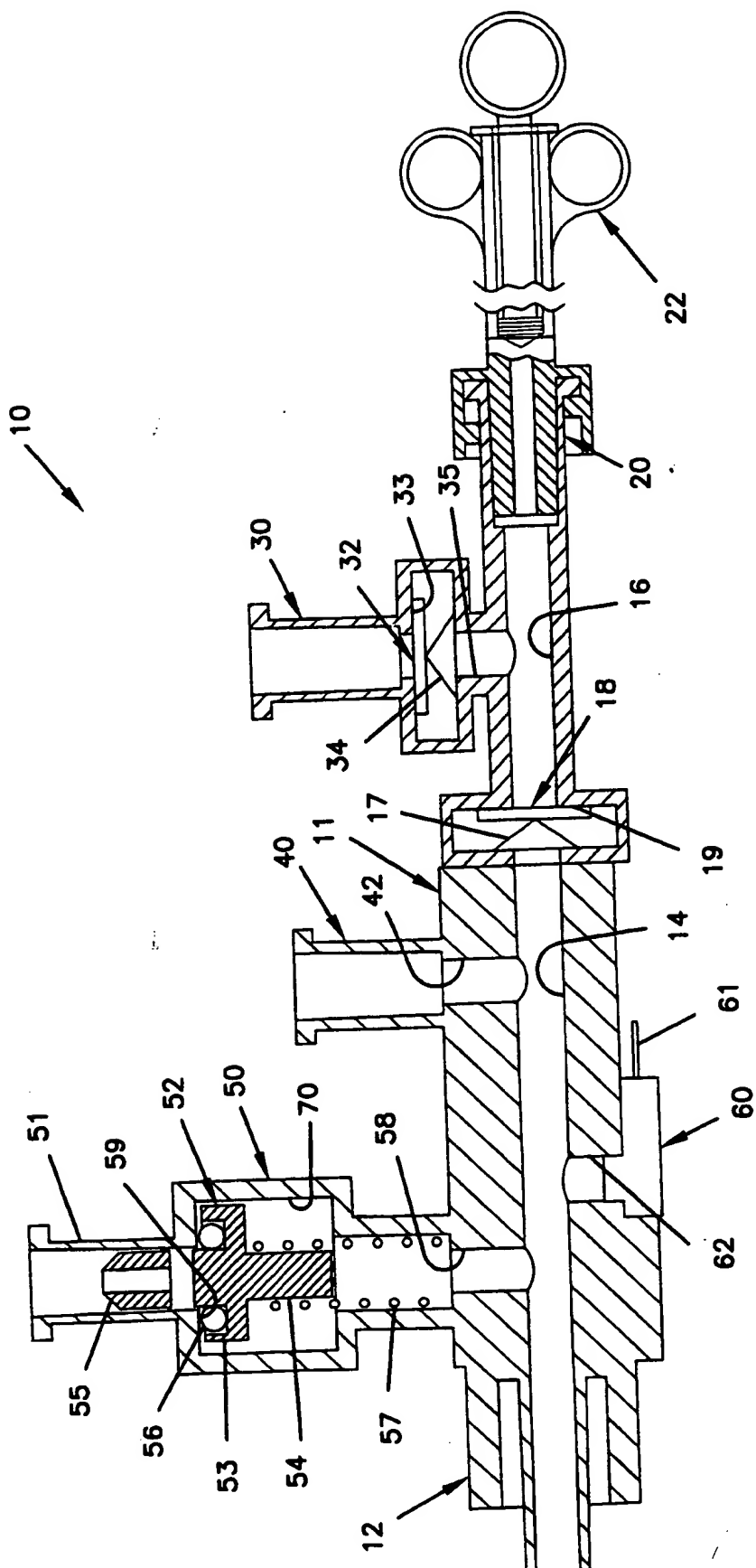
20. An automatic manifold according to claim 15, further including a pressure sensor integrated as part of the manifold.

15

21. An automatic manifold according to claim 15, wherein said injection means comprises a power injector.

22. An automatic manifold according to claim 15, wherein said injection means comprises a syringe.

FIG. 1



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INTERNATIONAL SEARCH REPORT

Int. Application No
PCT/US 99/21980

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M39/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 037 390 A (RAINES KENNETH ET AL) 6 August 1991 (1991-08-06) column 5, line 3 - line 5 column 5, line 37 -column 6, line 26 figures 2,10	1,2,5-9, 12,15, 16,19, 21,22
A	---	3,4,13
X	US 5 378 229 A (LAYER JAMES ET AL) 3 January 1995 (1995-01-03) column 4, line 32 -column 5, line 37 figure 2	1,2,8,9, 15,16, 21,22
A	---	3,17,18
	-/--	

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X	DE 196 43 360 C (MYERS JAN WILLEM MARINUS ING) 14 May 1998 (1998-05-14) column 3, line 62 -column 4, line 13 figure 1	1,2,5,6, 8,15,16
A	---	3
X	WO 96 24791 A (CHOKSI) 15 August 1996 (1996-08-15) page 4, line 7 - line 8 page 9, line 18 - line 28 figure 5	1,2, 14-17
X	---	
X	US 4 246 932 A (RAINES KENNETH) 27 January 1981 (1981-01-27) column 4, line 50 -column 5, line 42 figures 2,4	1,15,16
X	---	
X	US 4 729 401 A (RAINES KENNETH C) 8 March 1988 (1988-03-08) figure 3	1,15
A	---	
A	US 5 688 244 A (LANG) 18 November 1997 (1997-11-18) column 3, line 47 - line 54 column 3, line 62 - line 65 figures 3-5	10,11,20

INTERNATIONAL SEARCH REPORT

information on patent family members

Inte. onal Application No

PCT/US 99/21980

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5037390 A	06-08-1991	NONE	
US 5378229 A	03-01-1995	NONE	
DE 19643360 C	14-05-1998	NONE	
WO 9624791 A	15-08-1996	US 5727594 A	17-03-1998
US 4246932 A	27-01-1981	NONE	
US 4729401 A	08-03-1988	NONE	
US 5688244 A	18-11-1997	DE 4324230 A	26-01-1995
		DE 4340536 A	04-05-1995
		AT 168567 T	15-08-1998
		CA 2142598 A	02-02-1995
		DE 59406491 D	27-08-1998
		WO 9503079 A	02-02-1995
		EP 0660729 A	05-07-1995
		ES 2121201 T	16-11-1995